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QUALITY CONTROL OF RADIOACTIVITY-COUNTING SYSTEMS

H. E. Kolde

Public Health Service
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Radiological Health

QUALITY CONTROL OF RADIOACTIVITY-COUNTING SYSTEMS

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

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by

H. E. Kolde

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
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TABLE OF CONTENTS

	Page
Abstract	v
Introduction	1
Quality-Control Charts	1
Performance Standards	3
Basic Counting-Laboratory Requirements	5
Starting a Performance-Control Chart	5
Routine Conduct of Performance Tests	9
Background Control	10
Post-Repair Tests	14
Test Records	14
Calibration Control	14
Spectrometer Resolution	15
References	16

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ABSTRACT

Techniques for obtaining satisfactory performance from radioactivity-counting systems are described. Acceptable performance is maintained by routine tests of background and standards combined with the application of statistical criteria of acceptability. The use of control charts in conjunction with the test data is recommended to facilitate determination of satisfactory instrument and sample measurements. Corrective adjustments are made when necessary to assure continuity of reproducible results, which is particularly important for long-term studies. Methods of chart application and interpretation of plot patterns are outlined. Requirements for the design of counting laboratories, suitable performance standards, and associated control measures are also discussed.

INTRODUCTION

In a program involving intercomparison of sample-counting data it is essential to maintain constancy in the response of the nuclear-counting system. This is especially important in operations involving the validation of long-term studies. The application of suitable quality-control measures in the counting laboratory minimizes day-to-day operational variability and preserves the capability of conducting consistent, reproducible measurements.

The reliability of counting systems is maintained principally by regularly checking source response and background. Response is tested by means of a radioactive source, called a performance standard, which provides a live check of the entire counting system. This serves to minimize inherent fluctuations. Control of the background limits the range of variation and is necessary for precise measurement of comparatively low-level radioactivities where maximum sensitivity is desired. Continuous instrument control is assured by the application of quality-control chart techniques, as suggested by Bennett and Franklin (1) and used extensively by Covell (2) for maintaining gamma multichannel analyzer operation.

In this report procedures will be outlined for establishing and implementing test and control-chart techniques in the counting laboratory where various types of counting instruments (proportional, GM, and scintillation counters, and gamma multichannel pulse height analyzers) may be utilized, and where a variety of radionuclides, often at environmental levels, are analyzed. Also included, because they relate to achievement of thorough control, are brief summaries of requirements for selection of performance-standard radionuclides, design of counting laboratories, and calibration-control measures.

QUALITY-CONTROL CHARTS

Standarized quality-control chart techniques (3, 4) provide a basis for (a) judging when and how much correction of instrument operation is required, (b) reducing tolerances when desirable, and (c) anticipating or diagnosing faulty instrument behavior. The chart (fig. 1) consists basically of a graphic plot of test results arranged chronologically. The x- or time-axis is marked off in "days," covering as long a time duration as practical. The mean of a set of test data is

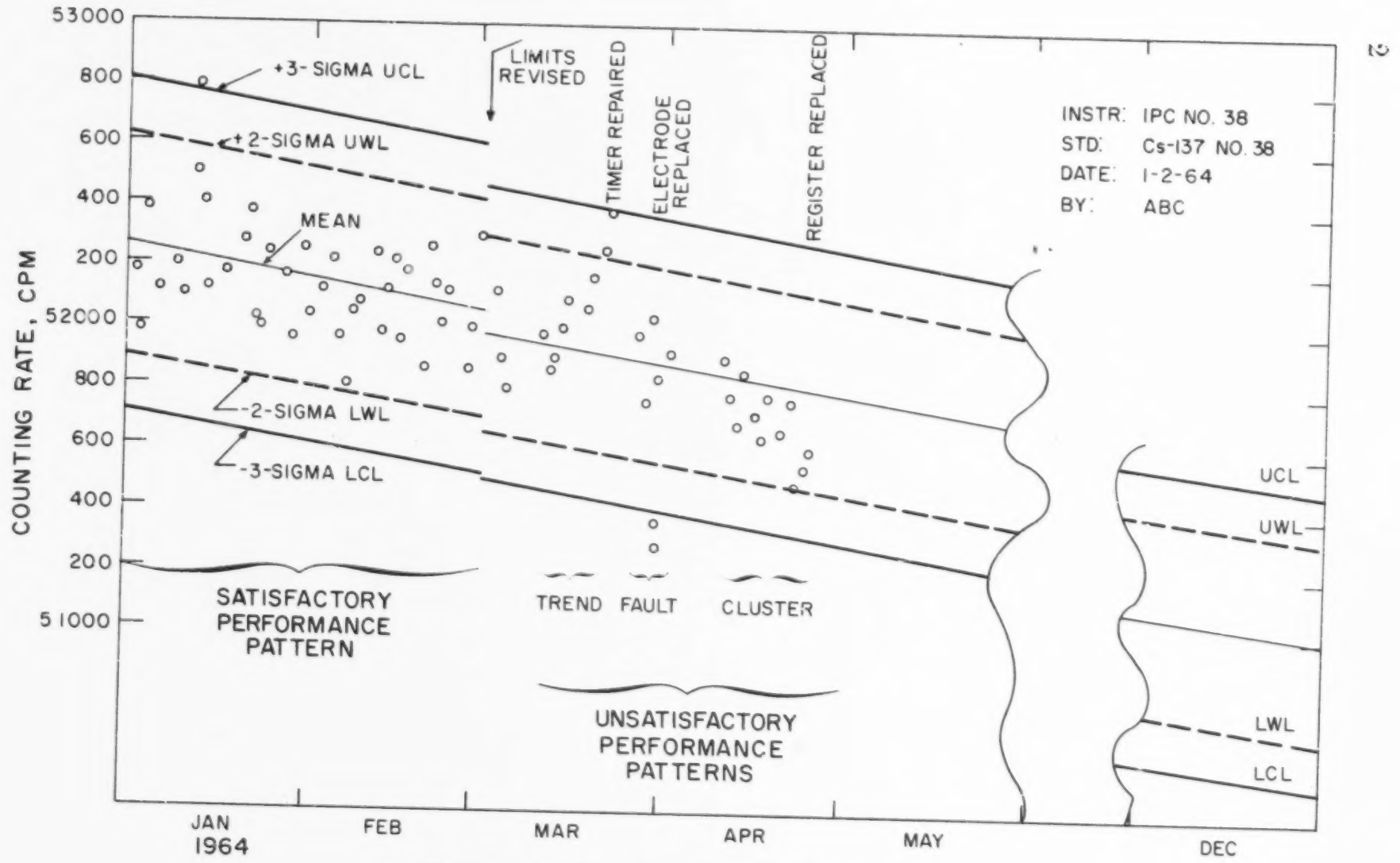

Figure 1. Typical performance control chart

plotted on the y-axis and extended across the graph. The plus and minus standard deviations of the data are plotted and drawn parallel to the mean line. The 3.0-standard-deviation error, or 3-sigma, level is taken to represent the limits of allowable variation. At the mean ±3-sigma interval, an average of only 27 out of 10,000 observations can be expected to fall outside the range from chance. The plus 3-sigma level is denoted as the *upper control limit* (UCL), the minus 3-sigma as the *lower control limit* (LCL). The ±2.0-standard-deviation errors are often utilized as warning levels (UWL and LWL), which assist in visual evaluations of the plot patterns. In this range, an average 1 out of 20 observations can be expected statistically to exceed the warning levels due to chance.

In routine chart applications, each test result is plotted and its position is compared with the control limits as well as with the previous points. The operation of an instrument is considered satisfactory whenever the points lie within the control limits and are randomly dispersed about the mean. Results falling outside the control limits indicate faulty performance and the need to remove the instrument from use. Potentially unacceptable performance can be anticipated by such indications as a series of points exhibiting a trend, consecutive points lying between the warning and control limits, or a long series or "cluster" of points lying consistently between the mean and one of the control limits.

Linear graph paper is preferred to semilog paper for performance and background control charts since logarithmic scales impose several construction difficulties, notably where a radioactivity level passes from one magnitude to another. Corrections are often necessary in control-chart construction to account for the decay of performance standards with less than 100-year half-lives during typical chart durations. Although radioactivity decay is an exponential function and its plot is curvilinear on linear paper, the error of its representation by a straight line is insignificant over a chart duration of 1 year whenever a radionuclide with a half-life of 10 or more years is used.

PERFORMANCE STANDARDS

Performance standards are radioactive sources used for maintaining the response consistency of counting systems. Since only the counting rate registered by an instrument is of interest, their absolute radioactivity does not have to be known, as is necessary for calibration standards.

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Radionuclides intended for this purpose should possess long half-lives for minimization of decay corrections. (Radionuclides with half-lives of 1 to 10 years may be used if the half-life value is accurately known.) An absolute requirement of the source material is absence of radioactive impurities that could affect the counting rate of the principal radionuclide (5). For example, the unrealized presence of a 2.07-year cesium 134 impurity in a 30-year cesium 137 standard will eventually cause discrepant decay-corrected cesium 137 counting rates because of the difference in their half-lives. The chemical nature of source material must also be considered so that occurrences such as hygroscopicity, creeping, volatilization, and atmospheric exchange do not introduce counting errors (6, 7). Disturbances of genetic relationships can be a problem in some cases, for example, in the partial isolation of parent and daughters in partly filled ampoules of radium 226 solutions.

The source material must be preserved by some sort of durable enclosure to prevent loss of radioactivity from handling. (Any standard that appears to have been damaged should not be used until its rating has been verified or redetermined after repairs.) All standards should be stored in separate repositories to eliminate the possibility of damage or contamination; shielding or remote storage may be necessary to minimize their contribution to instrument background levels. Maintenance of test reproducibility may require the use of holding-rings, spacers, or other devices for keeping the position of the standard constant with respect to the detector.

Suggested radionuclides for controlling beta-counting systems are cesium-barium 137, strontium-yttrium 90, or uranium oxide. Electrodeposited uranium oxide or americium 241 may be used for alpha counters. The use of radium DEF and thallium 204 for alpha or beta counter control is undesirable because their half-life values are currently in doubt. For checking gamma counters, any long-lived gamma emitter, such as 30-year cesium 137, may be used.

In view of their relatively low cost, it is generally advisable to have a standard available for each counting system in order to eliminate possible confusion as well as to reduce the time required for daily testing of the systems. Since it is not usually known at first whether an indication of unacceptable performance is due to instrument malfunction or to a damaged standard, it may be desirable to cross-rate a standard with another similar instrument or to have a master standard individually rated for each instrument.

BASIC COUNTING-LABORATORY REQUIREMENTS

Several layout and equipment requirements must be incorporated in the design of laboratories intended for performing assays of comparatively low-level samples. The room should be isolated from areas where relatively high-level radioactive sources are located. The temperature and humidity of the ambient laboratory air should be regulated, and the counting room kept under slightly positive pressure by means of a low-velocity air supply. Unless it is adequately filtered the air supply should not be recirculated from radioactive areas or spaces where the radon-thoron levels are higher than normal. The electrical power lines for the counting systems may require high-voltage regulators and noise suppressors. (Independent power sources such as motor-generators may be desirable in some cases.) Protection against electromagnetic interferences may be necessary. For example, desk calculators or other motors often emit radiofrequency signals that can be detected as spurious counts when operated in close proximity to some types of counting systems. The instrument gas supply should be checked before use to detect any radioactive impurities that could increase the normal background count. A continuously operating low-level radiation monitor which can be preset to alarm at specific levels may be desirable for guarding against the inadvertent introduction of radioactive materials that would affect the general background level. Good housekeeping practices should be continuously observed and the room kept as dust-free as possible as a precaution against the gradual buildup of contaminants.

A counting system preventive maintenance program based on the manufacturer's recommendations should be rigorously followed to anticipate and minimize deviations from acceptable operating conditions.

STARTING A PERFORMANCE-CONTROL CHART

The performance tests described below presuppose that a newly installed counting system has been preliminarily tested for operability and has been set up for routine operation. Acceptance can be determined by intercomparison with a similar instrument in the laboratory or, when this is not possible, by comparison of calibration results with the manufacturer's specifications or published data.

To establish a basis for routinely judging the acceptability of instrument operation, the most probable counting rate of the performance standard by the system must be determined initially. If this deter-

mination is made with satisfactory precision, the data may then be applied to the construction of the quality-control chart.

A reliable estimate of the mean counting rate and error for the standard is obtained by making repeated observations of equal time intervals in the counting system in which it will be used routinely. For gamma multichannel analyzers, the counting rate of the standard is based on a summation of the counts occurring within the entire photopeak selected. A minimum of 20 replicate measurements is recommended, with the standard being removed after each count to determine positioning effects. The source radioactivity should be sufficient to provide an observed total count with an error of ±1 percent at the 95-percent confidence level within a 1- to 10-minute counting period (but should not be so high that dead time is appreciable). Counting intervals of less than 1 minute should be avoided since a timer error may be introduced.

Counting observations are described by the Poisson distribution, and their mean and standard deviations are given by:

$$\overline{X}=\frac{\sum x_i}{n} \tag{1}$$

and

$$\sigma=\sqrt{\frac{\overline{X}}{t}} \tag{2}$$

where

$\overline{X}$=average counting rate
x_i=counting rate observed in any counting interval
n=number of observations
σ=standard deviation
t=counting duration of each observation

The theoretical counting error, given by Eq. (2), is then compared with its experimental value to determine whether the variation of results is distributed according to statistical expectation. This is accomplished by application of the chi-square (X^2) test (8):

$$X_n^2=\frac{\sum(x_i-\overline{X})^2}{\overline{X}/t}$$

The significance of the resulting chi-square value for n number of observations (or, more properly stated, for $n-1$ degrees of freedom) is determined by reference to the graph in figure 2 or chi-square tables given in many statistical textbooks. If the probability of occurrence is between 0.10 and 0.90, the variation of the test results is within statistical expectation and the data are acceptable. Chi-square values

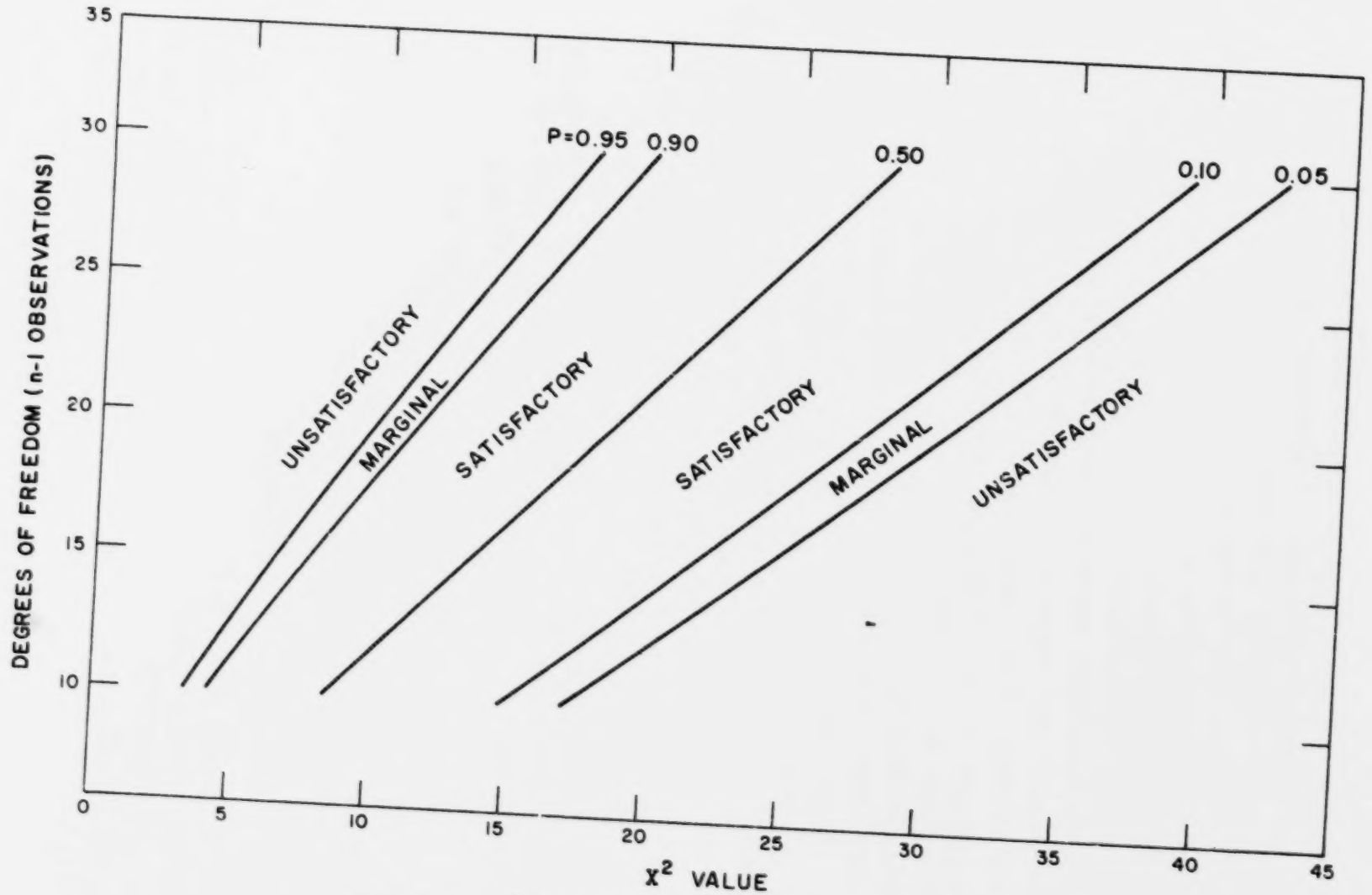

Figure 2. X^2 Distribution for reliability test of initial data for various probabilities, P

greater than 0.95 or less than 0.05 indicate that the results are too precise or too diverse, respectively. Faulty instrument setup or malfunctioning may be suspected primarily although the standard itself, its positioning, or a large background variation may be the cause. Values between 0.90 and 0.95 or 0.01 and 0.05 are marginally acceptable and should be used with caution.

Upon acceptance, the standard should be labeled with its observed count rating, date, and associated instrument identification. The mean counting rate and observed standard deviation values are applied to the construction of the control chart, as depicted in figure 1. The 2-sigma warning levels and 3-sigma control limits are determined by multiplying the observed standard deviation by 2 and 3, respectively. As previously discussed, the mean and control lines of the chart may have to be sloped negatively to account for performance source decay during the chart duration, depending upon the half-life of the radionuclide. For example, cesium 137 (with a half-life of 30 years) will decay approximately 1 percent every 5 months, which is a significant amount for charts of this duration. This adjustment may be accomplished simply by correcting the original mean for decay at the time represented by the end of the chart duration, plotting the value on the right y-axis, and connecting the two points by a straight line. The warning and control limits are drawn parallel to the mean.

In the beginning, the initial control chart mean and standard deviation values should be evaluated as each routine test result is plotted. These statistics should be redetermined if repeated adjustments are required to return the system to within control. When the initial test results lie within control but consistently on one side of the mean, the occurrence of a slight bias in the starting tests is indicated. The mean and control levels should be redetermined on the basis of a larger accumulation of data.

Example

The following example illustrates the methods of conducting the initial performance tests. A cesium 137 performance standard was counted 20 times. The necessary duration of each observation was determined to be 2 minutes to maintain a counting error of less than ±1 percent at the 95-percent confidence level for a standard that yielded an anticipated radioactivity of approximately 52,000 counts per minute. The individual results of the 20 observations were as follows, in counts per minute:

52377	52133	52680	52287
52202	52460	51972	52108
52102	52040	52441	52399
52385	52188	52153	52290
52427	52003	52388	52185

$$\text{Average } (\overline{X}) = \frac{1045220}{20} = 52261 \text{ cpm}$$

$$\text{Standard deviation } (\sigma) = \pm\sqrt{\frac{52261}{2}} = \pm 162 \text{ cpm}$$

$$\text{Warning levels} = \pm 2\sigma = \pm 324 \text{ cpm}$$

$$\text{Control limits} = \pm 3\sigma = \pm 486 \text{ cpm}$$

The observed data were chi-square tested:

$$X^2_{20} 630890 \div \frac{52261}{2} = 24.1$$

Figure 2 shows that a chi-square value of 24.1 for 20 measurements (19 degrees of freedom) is acceptable.

ROUTINE CONDUCT OF PERFORMANCE TESTS

Counting system response should be tested by using the performance standard prior to initiating sample counting and after the necessary calibration checks are completed. The test counting interval is of the same duration as that for the original rating of the standard, that is, long enough to provide a counting error of ±1 percent at the 95-percent confidence level. Each test result is immediately plotted on the control chart and its location compared with the warning and control levels as well as the previous points. Satisfactory operation is indicated by a pattern of points randomly dispersed about the mean and within the warning limits (although 1 of 20 results is statistically expected to fall outside the warning limits). Faulty operation is indicated by points falling outside the control limits; those located between the warning and control limits indicate marginally acceptable operation.

Any result located beyond the control limit should be immediately followed by a duplicate test to determine whether it is due to chance. When an unsatisfactory response is verified, the instrument control settings should be examined for correctness. Possible causes of malfunctions which can be readily checked are shifts in operating voltages or gain, detector damage, line noise, large background increases, or an erratic timer, scaling strip, or register. The standard itself should

be examined for wearing of the protective covering or leakage, which could cause increased or decreased counting levels, respectively. If the fault cannot be corrected, the instrument should be removed from routine operation until repaired.

The control charts should be continuously examined for indications of trends toward unacceptable operation so that potential malfunction of the instrument system or other sources of faults can be corrected as quickly as possible. For example, gradually decreasing counting rates may be caused by subtle degradation of a photomultiplier tube. Consecutive points within the control limit but lying consistently on one side of the mean may be symptomatic of potential faults. Slight losses of the source material within the standard are revealed by this condition. Each incurred fault and its method of correction should be noted on the chart to assist in analytical data evaluations or in the diagnosis of instrument malfunctions.

Closer tolerances can be obtained for more precise instrument control by calculating the mean and standard deviations of the initial and subsequently accumulated test data. Data derived from radioactive sources that possess half-lives requiring decay corrections in the chart construction must, however, be normalized for recalculation purposes. Such data can be grouped into equal time intervals, such as weekly or biweekly. The average counting rate of each group is determined and individually corrected to the same original time.

BACKGROUND CONTROL

The variations of counting system background levels are attributable not only to the daily and seasonal fluctuation of natural and artificially produced radionuclides but also to detector contamination or the observation of sources inadvertently introduced nearby. Such variations, if allowed, affect analytical precision and lessen the sensitivity for performing relatively low-level assays. The background response of each system must, therefore, be frequently measured to assure that the natural levels are within expected limits, and more importantly for low-level counting, to monitor for undesirable contributors. The frequency and duration of these measurements are determined by the range of fluctuation typically experienced; by requirements for analytical precision, bias, and sensitivity; and by the possibility of detector contamination from sample media. Various control aids are available for use in determining the occurrence of significant deviations from the normal background range.

A reasonably satisfactory estimate of the current normal background variation of a system can be obtained by completing 20 observations of equal counting duration. The interval of the individual counts should be long enough to provide a counting error of ±2.5 percent at the 95-percent confidence level. Counting periods of necessarily long duration may be made overnight or during weekends, provided that the background at such times has been found to be representative of levels occurring during working hours. The experimentally derived average background counting rate and standard deviation are calculated and tested for statistical acceptability according to the procedures described above for performance standards. Background control charts are constructed similarly (fig. 3). It should be noted in this regard that the experimental values may not be representative of the mean and range of background levels experienced at other times. This should be borne in mind when the background exceeds the control levels. The occurrence of large natural fluctuations may be verified by examining current background data from other systems.

Background should be routinely measured at least once each day, usually immediately after performance testing (unless long-duration tests are required). The counting interval is the same as that used for establishing the control chart. Test results exceeding the control limits should be verified by a duplicate test whenever possible. When the results indicate a significant background change from the normal range, the counting system should not be used until the cause has been identified. Primary causes of increased levels are detector contamination or a nearby radiation source. Occasionally, similar background increases detected by other counters may be due to a contaminated gas supply, line noise, or some other cause. If the condition cannot be eliminated feasibly and the levels are not excessive, revised control limits should be temporarily established until the levels revert to their normal values. The most recent background value should always be used for analytical data calculations.

Multichannel analyzer background can be adequately controlled by two diverse methods.

Significant contributors can be readily detected by means of a graphic overlay of the test background spectral plot and a master background spectrum derived from the averaged accumulation of many thousands of minutes of background counting. The fitted spectra are then examined for unusual photopeaks or other distortions in the shape of the peaks usually present. Figure 4 demonstrates a test spectrum that, when matched against its master spectrum, indicated the presence of a slight cobalt 60 contamination of the detector.

Subtle, gradually occurring changes in normal levels may be detected by examining total counts obtained in a low-energy portion of the

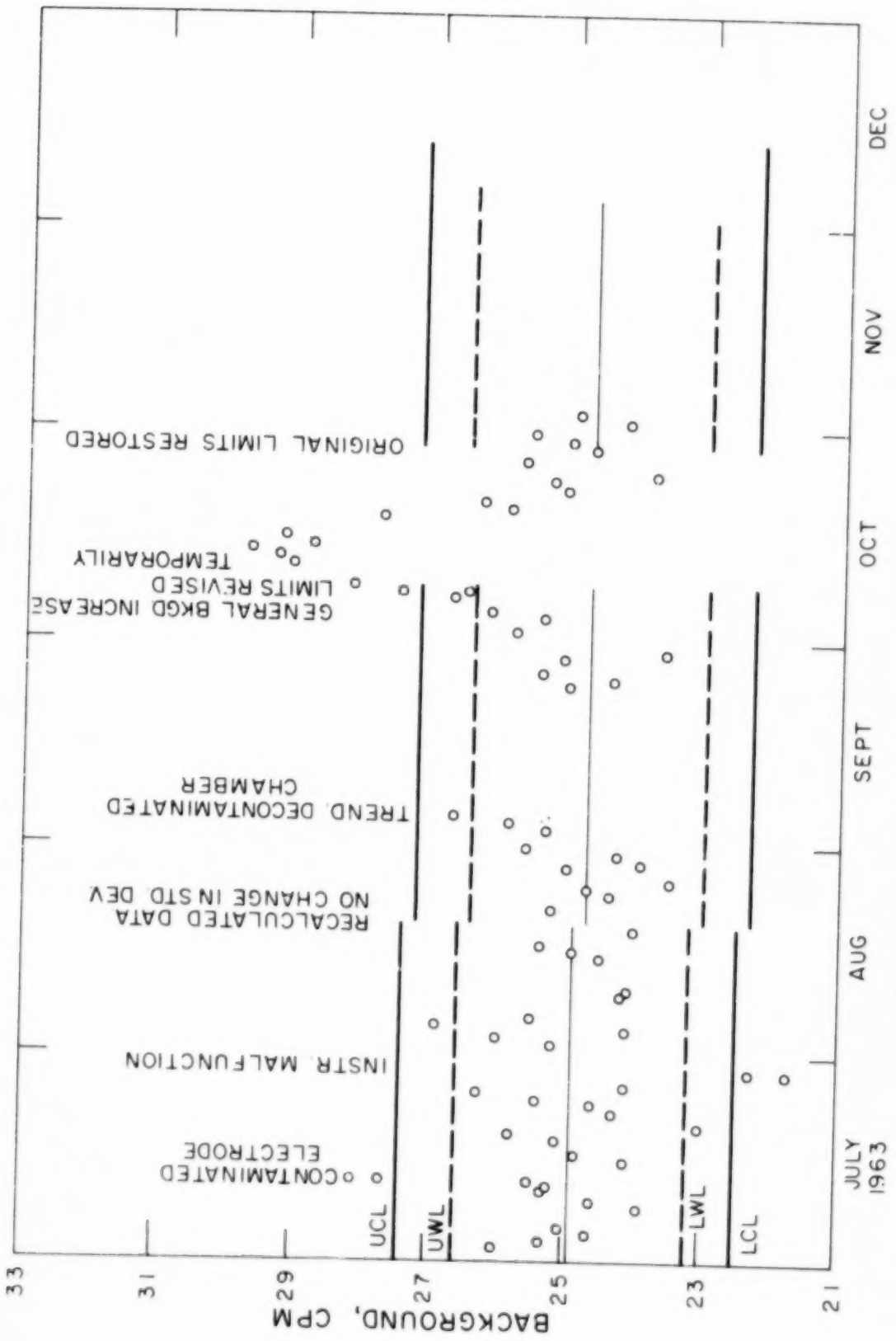

Figure 3. Typical background control chart

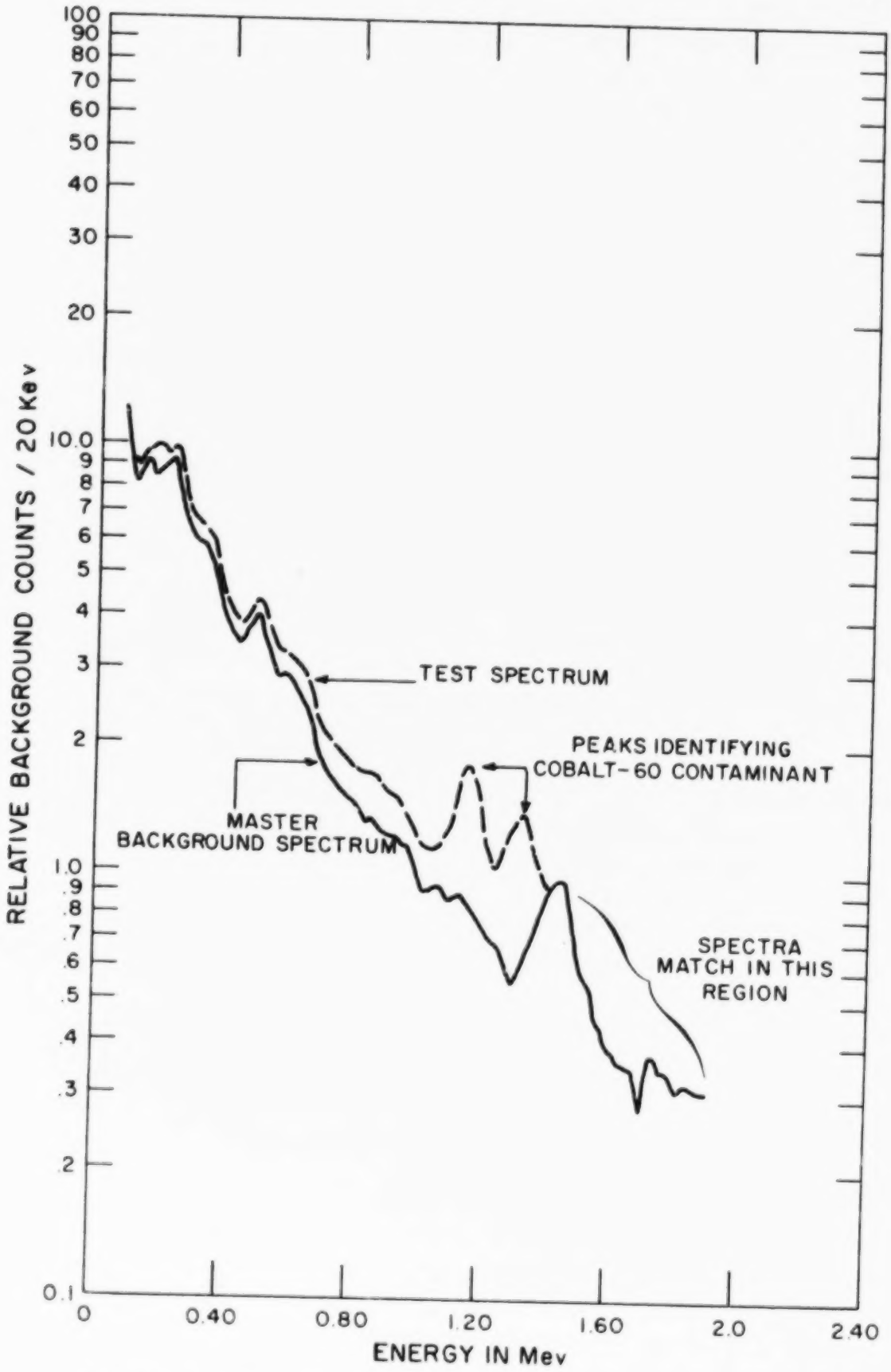

Figure 4. Results of comparative overlay of test background spectrum on master spectrum

spectrum, for example, in the band of 0.2 to 0.5 Mev. for gamma multichannel analyzers. Contaminants with energies greater than 0.2 Mev. will reveal their presence by photopeak or Compton contributions to this region. Control charts constructed on the basis of summations from 20 representative background measurements are useful for this type of control.

POST-REPAIR TESTS

A repaired or modified instrument system must be tested for acceptance before returning it to routine operation. At least one background and five performance checks should be conducted. The system can be considered fully satisfactory only when all test results duplicate their original control levels. Decreased background rates or counting efficiency increases within 5 percent indicate improved performance. In this case, new control limits and control charts must be established.

TEST RECORDS

Maintenance of detailed performance records also aids in subsequent analytical validity checks or diagnoses of instrument malfunctions. The types of data that should be entered are: background and performance test results, test counting durations, operating voltages, descriptions of incurred faults and corrective action, date and time, and name of the instrument operator. The results of special tests recommended by the manufacturer should also be included along with records of other preventive maintenance measures.

CALIBRATION CONTROL

Performance standards usually reveal deviations from established instrument calibrations. For certain types of counting systems, however, calibration standards are necessary for supplementary control.

Multichannel analyzers require energy alignment standards for maintaining correct zero baseline and gain settings. Radionuclides intended for this purpose must possess very accurately known radiation energy levels variously located in the spectral region of interest, particularly at the higher end of the range. Cesium 137 and cobalt

60 in combination have been found to be suitable for maintaining alignment of gamma spectrometers in the range of 0.1 to 1.5 Mev.

Spectrometers should be aligned before performance testing and as frequently during sample-counting operations as experience indicates to be necessary. The tolerable amount of shift depends upon the intrinsic capabilities of the detection system and the requirements for analytical precision. The alignment counting time should be of sufficient length to provide well-defined photopeaks. The radioactivity of the standard should be chosen with care because high counting rates can introduce spurious shifts, resulting in over-corrections when samples of much lower radioactivity are counted.

The voltage plateau shapes obtained with instruments such as proportional counters should be checked periodically since the response to the radiations of the performance standard may remain constant while changing for other energies of radioactivities that are being determined. The instrument can be periodically checked with calibration standards of the radionuclides of interest. When only one radionuclide is being analyzed, it may be desirable to use that isotope for the performance standard, provided that its half-life, purity, and chemical stability meet the requirements mentioned earlier. Radionuclides with radiations at the ends of the energy range concerned may also be used.

SPECTROMETER RESOLUTION

In conjunction with routine performance testing, the resolution of the detector and photomultiplier spectrometer components should be periodically examined to determine potential degradation. Gamma-spectrometer resolution is principally specified in terms of response to a cesium 137 point source. Plotting these data on the associated performance control chart may assist in anticipating and diagnosing faulty system operation.

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